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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,683	04/13/2000	Patrick Rivelli JR.	5877-0001.32	7036

490 7590 04/29/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,683

Applicant(s)

RIVELLI, PATRICK

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>15</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer (5,108,417) in view of Burton et al. (5,026,377). Sawyer discloses the method substantially as claimed. Sawyer, in figure 3, in col. 4, lines 14-25, and in col. 5, lines 3-11, disclose the method of treating a lesion as claimed, where a coiled-ribbon stent, forming a single conduit with downstream and upstream ends, inherently has a bending-stiffness gradient due to a gradient of ribbon thickness. Sawyer also discloses, in col. 4, lines 4-6, that the ribbon, when stretched out is straight (i.e. "a flat strip"). However, Sawyer does not specifically disclose application of the stent in a neurovascular target site and a neuro-interventional catheter. Sawyer also does not disclose a stent that is releasably attached to a pusher wire and the downstream end of the stent being engaged by the pusher wire. Sawyer does not disclose that the pusher

Art Unit: 3731

wire has an expanded portion and a notch connected to the stent. Sawyer also does not disclose stent diameters in the contracted-condition and the fully expanded position as claimed in claim 4, nor does Sawyer disclose, as claimed in claim 5, the surface area of a vessel region containing the stent. Burton et al. teach, in figures 1-3, a stent being delivered to a vessel with a pusher wire (9), where the pusher wire has an expanded portion (7) and a notch (13). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Burton et al., to apply a pusher wire in the delivery of Sawyer's stent to a vessel. Such a wire in a catheter would permit accurate placement of a stent within a vessel without snagging the catheter and/or the stent with the vessel wall during the stent deployment. Also, it would have been a matter of design choice to dimension (diameter and length) a stent as claimed in the contracted -condition and the fully expanded position, so that a surface area in a vessel region, as claimed, would be covered by the stent. It would also be a matter of design choice to dimension the catheter of Burton et al., so that the catheter can be applied to a neurovascular target site. The choice of a stent size and catheter size would be dependent upon the type and size of the vessel being treated and the size of a lesion being supported. It would be also obvious to apply Sawyer's stent to a neurovascular aneurysm, which is a type of "damaged vessel" (Sawyer, col. 5, lines 7 and 8), which can be successfully treated with a stent.

3. Claims 1, 5, 6, and 14-17 are rejected 35 U.S.C. 103(a) as being unpatentable over Kropf (4,760,849) in view of Burton et al. Kropf, in figure 4, in col. 2, lines 50-59, in col. 3, lines 8-20, and in col. 4, lines 9-20, discloses a method of treating a lesion with a

Art Unit: 3731

stent having a non-zero pitch (e.g., see fig. 2) and upstream and downstream ends and a bending-stiffness gradient due to a gradient of ribbon width and a gradient of size of openings (at 13 in fig. 1). Kropf's stent has dimensions as claimed in claims 5 and 6. For example, Kropf's stent can have a stent ribbon thickness of .5 mils; a lesser ribbon width (at midsection 11) of 5 mils (i.e., 2.5 mils of spring material width + 2.5 mils of opening width as seen in figure 4); and a greater ribbon width (at endsection 17 or 19), which is at least 10 times the ribbon thickness and at least two times the lesser width. However, Kropf does not specifically disclose guiding a neuro-interventional catheter to a neurovascular target site with a pusher wire. Burton et al. teach the guidance of a catheter to a target site for the deployment of a stent with a pusher wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Burton et al., to apply a catheter and pusher wire with the method of Kropf. Such a catheter and pusher wire would allow the safe delivery of a stent to a target site without undue damage to the vessel wall as the stent traverses the lumen of the vessel. It would also be obvious to dimension the stent and catheter of Kropf in view of Burton et al., so that the devices can be used at neurovascular target site. A neurovascular site is a luminal site that can have aneurysms treatable with stents.

Allowable Subject Matter

4. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3731

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses stent openings that are I-beam shaped or Z-shaped, where each of the "I" axis and the central axis of the "Z" is transversely aligned to the longitudinal axis of the stent in its contracted state.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

6. With respect to the rejections under 35 U.S.C. 103 and based on the references of Sawyer in view of Burton et al and Kropf in view of Burton et al. : See the rejections above. Also, with respect to the argument that the catheter of Burton et al. cannot be used with a coiled stent. The applicant should note that a braided stent is a type of an expandable, coiled stent in that the braid comprises intersecting helices or coils. In addition, the applicant is also reminded that Sawyer discloses, in col. 5, lines 3-5, a delivery catheter (previously cited U.S. Patent No. 4,665,918), similar to the catheter of Burton et al., that can be used with expandable coiled stents.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3731

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3731

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

April 27, 2004